

REMARKS

Claims 52-63 and 65-68 are pending. Applicants gratefully acknowledge the withdrawal of previous rejections made under 35 U.S.C. § 112, second paragraph. Applicants respectfully request entry of the amendments in claim 52, which place the claims in better form for allowance.

The Office rejected claims 52-63 and 65-68 under 35 U.S.C. § 103(a), as allegedly being unpatentable under Sheehan (U.S. patent 4,164,445) in view of Microbiology, fourth edition (Pelezar *et al.* at pages 858-856). In particular, the Office indicated that the previously pending claims use “comprising” language, and therefore does not exclude alcohols. (Office action, page 3). To expedite prosecution and for clarity, Applicants have amended claim 52 to define a carbon source consisting essentially of a carbohydrate, glycerol, a vegetable oil, or a hydrocarbon, wherein the fermentation medium may contain an amount of complex carbon and/or nitrogen source that is at most about 10 % of the total amount of carbon and/or nitrogen.

Unlike the invention as claimed, Sheehan teaches the use of ethanol as the major source of carbon and energy in the biosynthesis of penicillins. (See Sheehan patent at col. 1:45-47 and claim 1). The Office also indicated that Sheehan uses 10 % ethanol and 1.8 % corn steep liquor. In the absence of ethanol, the carbon sources used in Sheehan are cornsteep liquor (1.8 %), and glucose hydrate (0.20 %). (See Sheehan patent at col. 3:2-15). As indicated in the specification, cornsteep liquor is a complex carbon source. (See, specification at page 1, lines 21-24). Thus, the carbon source in Sheehan, in the absence of ethanol, is primarily composed of corn steep liquor, a complex carbon source. In contrast, the carbon source in the invention as claimed consists essentially of carbohydrate, glycerol, a vegetable oil, or a hydrocarbon.

Even if combined with the Microbiology reference, the combination fails to teach the invention as claimed. As shown in Figure 40-4, the Microbiology reference teaches the manufacture of penicillin using a medium of corn-steep liquor, lactose, salts and other ingredients. However, the Microbiology reference does not teach the percentage composition of the fermentation medium, let alone a fermentation medium comprising a carbon source consisting essentially of carbohydrate, glycerol, a vegetable oil, or a hydrogen; and an amount of complex carbon and/or

nitrogen source that is at most about 10 % of the total amount of carbon and/or nitrogen sources. If combined with the Sheehan patent, the fermentation medium would comprise primarily of a complex carbon source (*i.e.*, 1.8 % of cornsteep liquor and 0.20 % of lactose).

Because Sheehan, alone or in combination with the Microbiology reference, fails to teach all the elements of the invention as claimed, the claims are non-obvious. Furthermore, there is no reasonable expectation of success that a fermentation medium comprising an amount of complex carbon and/or nitrogen source that is at most about 10 % of the total amount of carbon and/or nitrogen sources may be used for large scale β -lactam production. As indicated in the specification, the product yields which would be obtained using chemically defined media on an industrial scale were typically considered to be substantially lower than those obtained using media containing complex raw materials. In addition, high-producing microbial strains which have been developed for industrial processes in complex media were suspected not to retain their good performance in chemically defined media. (See, Specification at 2:34-3:7).

Based on the above, the claims are nonobvious. Thus, Applicants respectfully request that the rejections under 35 U.S.C. § 103 be withdrawn, and the claims be passed to allowance.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 246152012710. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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